

**PSJ14 Janssen Opp Exh 65 – ABDCMDL00003659**



U. S. Department of Justice  
Drug Enforcement Administration  
8701 Morrisette Drive  
Springfield, Virginia 22152

[www.dea.gov](http://www.dea.gov)

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Dear Registrant:

This letter is being sent to every entity in the United States who is registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. This letter is to remind controlled substance manufacturers and distributors of their responsibility to inform DEA of suspicious orders in accordance with 21 Code of Federal Regulations (C.F.R.) § 1301.74(b).

On September 27, 2006, DEA sent a letter to this registrant community expressing concerns regarding drug abuse in the United States and highlighted the responsibility of manufacturers and distributors to be vigilant in the distribution of controlled substances. To assist manufacturers and distributors, DEA listed circumstances that might be indicative of diversion. On December 27, 2007, DEA issued another letter which reiterated the responsibility of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b). Although DEA's September 2006 letter included a list of factors that might indicate diversion, DEA wants to stress that this was not a comprehensive list of all possible indications of diversion. DEA encourages registrants to take an integrated approach. This point was emphasized in the December 2007 letter, and DEA is once again bringing it to your attention.

Under federal law, all manufacturers and distributors are required to maintain effective controls against diversion. 21 United States Code (U.S.C.) § 823. DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Specifically, 21 C.F.R. § 1301.74(b) states, "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances." This regulation clearly places the responsibility on the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders.

The registrant is also required to inform the local DEA Field Division Office of suspicious orders when discovered. The regulation provides examples of suspicious orders such as orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants who rely on rigid formulas to identify whether an order is suspicious may fail to detect suspicious orders. For example, this system might not identify suspicious orders placed by a pharmacy, if that pharmacy placed unusually large orders from the beginning of its relationship with the supplier. This system might not identify orders as suspicious if the orders were solely for one highly abused controlled substance. It should be noted that ordering one highly abused controlled substance and little or nothing else may indicate a deviation from the normal pattern of what pharmacies generally order.


When reporting an order as suspicious, registrants must be clear in their communications with the DEA Field Division Office that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant to their local DEA office and labeled as "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports." If the registrant determines the order is suspicious, the order may not be shipped and this suspicion must be reported to the local DEA Field Division Office.

Registrants who routinely report suspicious orders, yet fill these orders without first ascertaining that the order will not be diverted into other than legitimate medical, scientific, or industrial channels, are failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration. DEA may also pursue civil and criminal sanctions.

For more information regarding your obligation to report suspicious orders pursuant to 21 C.F.R. § 1301.74(b), please review the Final Order issued by the DEA Deputy Administrator in the matter of Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007). This document reiterates the duty to report suspicious orders when discovered by the registrant, and provides some criteria to use when determining whether an order is suspicious. The Final Order also specifically discusses a registrant's obligation to maintain effective controls against the diversion of controlled substances. You may obtain a copy of this Final Order, along with other information provided by the Office of Diversion Control, at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov).

As always, it is DEA's goal to work in cooperation with the regulated community. DEA seeks to educate its registrants on their responsibilities and obligations under federal laws and regulations to ensure that controlled substances are used for legitimate purposes and to prevent diversion. Your role in the proper handling of controlled substances is critical for public safety as it helps to protect society against drug abuse and diversion.

Sincerely,

  
Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control